DEC 19 2011

Summary of safety and effectiveness

In accordance with Section 513 (1) of the SMDA as defined in 21CFR part 807.3 this summary is submitted to obtain Pre-Market 510 (K) notification.

1. Submitter / Contact person.

Mr. Young Chi, President
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111 Ellison Street, Paterson, NJ 07505. U.S.A.
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2. Manufacturer

Dae Shin Enterprise.
401/2, 170-5 Gruo-dong, Guro-gu, Seoul, Korea
Tel: 2 2025 1151 Fax : 2 2025 1154
Contact: K. Kim President

3. Name of Device

Trade name	:	MX-7000 MICROXEL
Classification name :	:	Powered, Laser surgical instrument with Micro-beam/Fractional output
Common name	:	CO2 Laser system
Regulation	:	880.4810
Class	:	II
Product Code	:	ONG
Subsequent product code	:	GEX

4. Legally marketed Predicate Device

K100610	eCO2 Plus Laser	Lutronic
K100590	Edge CO2 Laser,	JM Systems

5. Device Description

MX-7000 Laser system utilize a Co2 module to generate a laser beam with wave length of 10.600 nm and used fractional or non fractional mode for different indication. The Doctor can optimize the effect for different applications by controlling the power of laser pulse and using different hand pieces.

The system are supplied with two hand pieces (Scanned or/and Dynamic),depend the device configuration

This system consist of

Optic main Bench assembly, Articulated Arm
LCD control panel, Laser Cooling system
Hand pieces set, Foot Pedal switch.

Manufactured in accordance with both mandatory and voluntary standard

IEC 60601 Medical Electrical equipment part 1.
General requirement for safety amend 2 1995
IEC60601-1-2 Electro magnetic compatibility test ED 2001 EMC test
IEC60601-1-22-22: 1996 Particular requirement for the safety and Diagnostic of Therapeutic laser Equipment

6. Intended use

MX-7000 CO2 laser system is indicated for use in non-fractionated mode is Incision, Excision, Ablation, Vaporization, and Coagulation of Human body soft Tissues. This system can be used in Dermatology, Plastic surgery, General surgery, Gynecology, Neurosurgery, and in Podiatry.

When used in fractionated mode, the MX-7000 CO2 system is indicated for use ablative skin re-surfacing, Wrinkle, Fine line, Rhylides,
Furrow in Dermatology, Plastic surgery, and in General surgery.

7. Conclusion.

The D.S.E, MX-7000 Co2 system, in this submission, is substantially equivalent to several already cleared predicate device in respect to Intended use, Main function, Technology, Principal operation and performance.

So, it does not raise any additional concerns regarding safety and effectiveness.

Bio-Med USA will update and include in this summary any other information deemed seasonally necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 19 2011

Bio-Med USA, Inc.
% Mr. Young Chi
President
111 Ellison Street
Paterson, New Jersey 07505

Re: K111831
Trade/Device Name: MX-7000, Microxel
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and Plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONG, GEX
Dated: September 02, 2011
Received: December 13, 2011

Dear Mr. Chi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for use statement

510 (K) number : K111831

Device name : MX-7000, MICROXEL

Indication for use : MX-7000 CO2 laser system is intended for use in non-fractionated mode for Incision, Excision, Ablation, Vaporization, and Coagulation of Human body soft Tissues. This system can be used in Dermatology, Plastic surgery, General Surgery, Gynecology, Neurosurgery, and in Podiatry.

When used in fractionated mode, the MX-7000 CO2 system is intended to be used for ablative skin re-surfacing, Wrinkle, Fine lines, Ryhhides, Furrow in Dermatology, in Plastic surgery, and in General surgery.

Prescription use ______xx______________ or/and Over the Counter use________________________
(Part 21 CFR 801 Sub part D) (Part 21CFR 801 Sub part C)

Please do not write below line-continued an another pages if needed

Concurrence of CDRH, office of Device Evaluation (ODE)

Neil R P Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111831